Claims 32-43 are rejected under 35 U.S.C. § 102(b) as being anticipated by EP-A 711 557 or WO 96/37192.

Claims 32-43 are rejected under 35 U.S.C. § 102(a) as being anticipated by EP-A 852 941 or WO 97/21428.

Claims 32-43 are rejected under 35 U.S.C. § 103(a) as being unpatentable over EP-A 349 150 or EP-A 711 557 or EP-A 852 941 or WO 96/37192 or WO 97/21428.

Claims 37-43 have been amended.

Claims 37-43 are presented for reconsideration.

REMARKS

Claims 32-43 are pending.

Claims 37-43 have been amended by replacement. No other claims have been amended. No claims have been added.

Another version of the amended claims, showing the changes relative to the previous version, is appended. Additions are shown by underlining. Deletions are shown by strikethrough rather than bracketing since the claims may contain bracketing that is to remain. No new matter has been added.

Claims 32-43 are rejected under 35 U.S.C. § 112, second paragraph as indefinite, the examiner questioning what is meant by ", in which any cosmetically active agent is lipophilic and is always present *as* component (c)" in claim 32. Applicants respectfully note that the passage in question actually states, ", in which any cosmetically active agent is lipophilic and is always present **in** component (c)". This means that (c) is the lipophilic component and comprises a natural or synthetic or a partially synthetic C_4-C_{18}triglyceride and a lipophilic cosmetically active agent, and any cosmetically active agent present is lipophilic (as opposed to hydrophilic) and is always present in component (c). Applicants aver that this meaning is quite clear and definite.

The examiner also comments that claim 32 recites "which steps consist essentially of". The examiner asserts that claims 37-43 require additional steps and are therefore improper. Responsive thereto applicants have rewritten claims 37-43 as product-by-process claims. Applicants note that there is nothing improper or indefinite in referring to a claim of a different statutory class for a definition of a term. See *Ex parte Porter*, 25 USPQ2d 1144 (BPAI, 1992).

Re claim 43, page 17 of the disclosure states:

> Solid forms of presentation contain the nanodispersion in the dehydrated form, the dehydration of the nanodispersion usually being carried out by freeze-drying or spray-drying in the presence of customary auxiliaries.

Hence no new matter has been added.

It is respectfully submitted that all the claims submitted for reconsideration are in good formal order. Reconsideration and withdrawal of the rejection of claims 32043 under 35 U.S.C. §112, second paragraph is therefore solicited.

Claims 32-43 are rejected under 35 U.S.C. § 102(b) as being anticipated by EP-A 349 150, of record and under 35 U.S.C. § 103(a) as obvious. The examiner asserts that the reference discloses the instant formulations (no formulations are claimed) and method. However this assertion is incorrect. Applicants note page 5, lines 22-25, of the EP, where a homomixer is first used, "the component 6 [deionized water, mis-numbered in Table 1 since there are two 3)s -see Table 3] was gradually added, and a pressure emulsification was carried out by a Manton Gaulin."

As is well known, a Manton Gaulin is a high-pressure nozzle homogenizer, which is typically operated at a pressure of several hundred bar (= several thousand pounds per square inch). As evidence of this, the examiner is requested to consider the attached posting at ProcessPlant.com wherein a typical Manton Gaulin high-pressure homogenizer is offered for sale. Note that this unit has a very powerful 15,000-watt motor, and it was operated at **345 bar** (= about five thousand pounds per square inch!) to generate high cavitation, shear and impingement forces. Almost 30 years ago the undersigned used a similar Manton Gaulin homogenizer, operated under a pressure of about 3,500 psi, to prepare pilot plant quantities of epoxy resin emulsions.

On page 4, lines 37ff the EP explains what a "strong shearing force treatment" means:

> ... the treatment in which an emulsifier capable of providing a stronger or higher shearing force than a mixer ... preferably operating under a pressure of 500 psi or more, more preferably 2000 psi or more, a colloid mill preferably operating at 1000 rpm or more, more preferably 5000 rpm or more, or an ultrasonication emulsifier.

Thus, in the step which corresponds to step (β) in claim 32, "*adding the liquid obtained in step (α) to a water phase, wherein step (β) is carried out in the absence of high shear or cavitation forces*," EP A 349 150 clearly teaches and exemplifies the exact opposite! Therefore, EP A 349 150 clearly neither teaches nor suggests the inventive process or the product-by-process physical forms obtainable thereby.

Reconsideration and withdrawal of the rejection of claims 32-43 under both 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) over EP A 349 150 is respectfully solicited in light of the remarks *supra*.

Claims 32-43 are rejected under 35 U.S.C. § 102(b) as being anticipated by EP-A 711 557 or WO 96/37192, both of record. However EP-A 711 557 uses no ethanol. and the subsequent mixing is with a Rannie High-Pressure Laboratory Homogenizer (see page 8, line 20). Therefore, EP A 711 557 clearly neither teaches nor suggests the inventive process or the product-by-process physical forms obtainable thereby.

WO 96/37192 is directed to the preparation of the pharmaceutical or cosmetic compositions comprising a sparingly soluble sphingolipid or glycolipid. Said compositions comprise:

a) a sphingolipid or glycolipid,
b) a phospholipid,
c) a partial fatty acid ester,
d) a carrier liquid,
e) a therapeutic agent,
f) a triglydceride and
g) a water-soluble or lipid-soluble additive.

The carrier liquid d) is "water optionally admixed with C_2-C_4-alkanol" (page 13, line 5 of the WO). WO teaches to use 1 to about 10% of ethanol for injectable pharmaceutical formulations, but for cosmetic formulations, ethanol, isopropanol or mixtures thereof may be optionally admixed as C_2-C_4-alkanol.

The amount of C_2-C_4-alkanol to use for cosmetic formulations is from 0.1 to about 10 %, with 0.1 to 2.0 % being preferred (page 13, lines 15-18).

On page 18, first paragraph of the WO, the preparation of the pharmaceutical or cosmetic compositions is disclosed. The process consists of 2 steps:

1. mixing components a), b), c) and d) and the optional components e), f) and g) and subjecting the dispersion to the steps

2. α) addition of water (carrier), or

   β) filtration and optionally dialysis and subsequent conversion of the dispersion into a dry preparation, or

   γ) further processing the dispersion to the intended pharmaceutical dosage.

This is clearly distinguished from the specific preparation process of the present invention wherein addition of the nanodispersion prephase **to** the water is required.

Reconsideration and withdrawal of the rejection of claims 32-43 under 35 U.S.C. § 102(b) as being anticipated by EP 711 577 or WO 96/37192 as applied to the instant claims is respectfully solicited in light of the remarks *supra*.

Claims 32-43 are rejected under 35 U.S.C. § 102(**a**) as being anticipated by EP-A 852 941 or WO 97/21428, both supplied by applicants. The examiner states, "These rejections will be reconsidered upon submission of the English translations". However, when applicants supplied both references, they clearly identified them as cited on the EP Search Report in the IDS mailed on August 4, 1999. Applicants have no obligation to have references that are cited in a foreign Search Report translated into English. Nevertheless, they provided a copy of U.S. Patent 5,997,888, which is an English language equivalent of EP-A 852 941, and they enclose herewith a copy of CA 2,238,263, which is an English language equivalent of WO 97/21428.

EP-A 852,941 (= U.S. Patent 5,997,888) discloses a cosmetic preparation comprising

a) an oil-soluble active agent,

b) a partial fatty ester of polyoxyethylene sorbitan,

c) at least one phospholipid,

d) ethanol and

e) water as carrier (see abstract).

The composition is obtained by dissolving component c) (phospholipid) in ethanol and adding components b) and a) and stirring the mixture.

The nanodispersion is obtained by adding the lipophilic phase consisting of components a), b), c) and d) and optionally further lipophilic ingredients f) to an aqueous phase e).

In contrast thereto the nanodispersion obtained by the process of the present invention comprises as essential component c) a triglyceride. This is neither taught nor suggested by EP-A 852,941.

WO 97/21428 (= CA 2,238,263) discloses a pharmaceutical composition for the dermal application of cortisone. The composition comprises a) the active agent (= cortisone), b) a partial fatty acid ester of polyoxyethylene sorbitan, c) a phospholipid, d) a triglyceride, e) water, and optionally f) adjuvants for dermal application.

The composition is obtained by mixing the components a)-d) with the aqueous carrier which optionally contains component f) and optionally filtration of the nanodispersion and/or further processing of the nanodispersion to a dermal preparation.

In contrast thereto in the method of the present invention the phospholipid, polyoxyethylene emulsifier, the triglyceride, the lipophilic cosmetic agent and ethanol are mixed. The liquid so obtained is added to the water phase. This is neither taught nor suggested by WO 97/21428.

Reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(a) as being anticipated and under 35 U.S.C. § 103(a) as obvious over EP-A 852 941 or WO 97/21428 as applied to the instant claims is respectfully solicited in light of the remarks *supra*.

Claims 32-43 are rejected under 35 U.S.C. § 103(a) as being unpatentable over EP-A 349 150 or EP-A 711 557 or EP-A 852 941 or WO 96/37192 or WO 97/21428, cited above. Each of these references have been distinguished above and it has been shown that they neither teach nor suggest the present invention. Reconsideration and withdrawal of these rejections is therefore respectfully solicited in light of the remarks *supra*.

Since there are no other grounds of objection or rejection, passage of this application to issue with claims 32-43 is earnestly solicited.

Applicants submit that the present application is in condition for allowance. In the event that minor amendments will further prosecution, Applicants request that the examiner contact the undersigned representative.

Respectfully submitted,

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Enclosures: Form PTO-1449, 2 references, Petition for Extension of Time

APPENDIX: Marked up version of amended claims.

37. (amended) A ~~method of preparing a~~ cosmetic formulation ~~of a lipophilic cosmetic active agent in the form of an aqueous nanodispersion, wherein the cosmetic formulation is~~ in the form of a gel ~~which comprises~~ having incorporated therein a nanodispersion as defined in claim 32 comprising a lipophilic cosmetic active agent.

38. (amended) A ~~method of preparing a~~ cosmetic formulation ~~of a lipophilic cosmetic active agent in the form of an aqueous nanodispersion, wherein the cosmetic formulation is~~ in the form of a cream, lotion or milk ~~which comprises~~ having incorporated therein a nanodispersion as defined in claim 32 comprising a lipophilic cosmetic active agent.

39. (amended) A ~~method of preparing a~~ cosmetic formulation ~~of a lipophilic cosmetic active agent in the form of an aqueous nanodispersion, wherein the cosmetic formulation is~~ in the form of a stick ~~which comprises~~ having incorporated therein a nanodispersion as defined in claim 32 comprising a lipophilic cosmetic active agent.

40. (amended) A ~~method of preparing a~~ cosmetic formulation ~~of a lipophilic cosmetic active agent in the form of an aqueous nanodispersion, wherein the cosmetic formulation is~~ in the form of a spray or aerosol ~~which comprises~~ having incorporated therein a nanodispersion as defined in claim 32 comprising a lipophilic cosmetic active agent.

41. (amended) A ~~method of preparing a~~ cosmetic formulation ~~of a lipophilic cosmetic active agent in the form of an aqueous nanodispersion, wherein the cosmetic formulation is~~ in the form of a foam ~~which comprises~~ having incorporated therein a nanodispersion as defined in claim 32 comprising a lipophilic cosmetic active agent.

42. (amended) A ~~method of preparing a~~ cosmetic formulation ~~of a lipophilic cosmetic active agent in the form of an aqueous nanodispersion, wherein the cosmetic formulation is~~ in the form of a paste ~~which comprises~~ having incorporated therein a nanodispersion as defined in claim 32 comprising a lipophilic cosmetic active agent.

43. (amended) A ~~method of preparing a~~ cosmetic formulation ~~of a lipophilic cosmetic active agent in the form of an aqueous nanodispersion, wherein the cosmetic formulation is~~ in the form of a powder,

lacquer, pellet or cosmetic make-up ~~which comprises~~ having incorporated therein a nanodispersion as defined in claim 32 comprising a lipophilic cosmetic active agent in which the nanodispersion is present in dehydrated form.